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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

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EXAMINER	
TSOY, ELENA	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,216	RICHARD, ROBERT E.	
	Examiner	Art Unit	
	Elena Tsoy	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 21-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12-15* is/are allowed.

6)☒ Claim(s) *1-11 and 21-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. Amendment filed on January 19, 2005 has been entered. Claims 1-15, 21-32 are pending in the application.

Claim Objections

2. Objection to claim 24 because of the informalities has been withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3-5, 7, 9, 11, 21, 22, 28-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner (EP 405 284 A2) in view of Allen et al (US 6,495,204) and Smith (US 4,734,451) for the reasons of record as set forth in Paragraph No. 5 of the Office Action mailed on October 19, 2004 because ejection port of amended claim 3 reads on nozzle of claim 28.

5. Claims 2, 23-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner (EP 405 284 A2) in view of Allen et al (US 6,495,204) and Smith (US 4,734,451), further in view of Scott et al (US 5,383,928), and further in view of Lambert (US 5,900,246) and Davidson (US 5,954,724) for the reasons of record as set forth in Paragraph No. 6 of the Office Action mailed on October 19, 2004.

6. Claims 6, 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner (EP 405 284 A2) in view of Allen et al (US 6,495,204) and Smith (US 4,734,451), further in

view of Mehta et al (US 6,627,246) for the reasons of record as set forth in Paragraph No. 7 of the Office Action mailed on October 19, 2004.

7. Claims 8, 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner (EP 405 284 A2) in view of Allen et al (US 6,495,204) and Smith (US 4,734,451), further in view of Scott et al (US 5,383,928), further in view of Lambert (US 5,900,246) and Davidson (US 5,954,724), and further in view of Mehta et al (US 6,627,246) for the reasons of record as set forth in Paragraph No. 8 of the Office Action mailed on October 19, 2004 because amendment of claim 8 does not change the scope of the claim since claim 1 recites that a therapeutic is interfaced with a SCF prior to transferring the therapeutic from SCF to the medical device.

Allowable Subject Matter

8. Claims 12-15 are allowed for the reasons of record as set forth in Paragraph No. 9 of the Office Action mailed on October 19, 2004.

Response to Arguments

9. Applicants' arguments filed January 19, 2005 have been fully considered but they are not persuasive.

(A) Applicants argue that none of the cited references disclose or suggest "transporting, within a conduit, the interfaced therapeutic and supercritical fluid towards a medical device," as recited in claim 1, and neither Allen nor Smith can remedy Greiner because neither Allen nor Smith is relevant prior art as neither of them teaches the use of a therapeutic or the coating of a medical device.

The Examiner respectfully disagrees with this argument.

Greiner teaches a method of coating a catheter (claimed medical device) with therapeutic by transferring the therapeutic to the medical device from a *mixture* of the therapeutic (chemical modifier) and SCF (i.e. therapeutic interfaced with supercritical fluid) using a **batch soaking in an enclosed chamber** (See column 2, lines 1-8).

Allen et al teach that it is well known in the art to use either ***spraying*** **from a pressurized chamber through a narrow** ***nozzle*** or **batch soaking in an enclosed chamber** (See column 2, lines 1-6) to coat elongated materials (See column 1, lines 65-67) using a *mixture* of the chemical modifier and SCF (See column 4, line 15). Allen et al teach that the typical spray deposition of the prior art is shown at Fig. 4a of US 4,734,451 to Smith (See column 2, lines 1-25)

Smith teaches that the typical spray deposition of a coating material on **any** given **substrate** (See column 2, lines 60-61) comprises combining coating material with SCF upstream of control valve (See column 14, lines 20-23), transporting the interfaced coating material within a conduit toward the medical device, spraying the interfaced coating material through nozzle 226 (See column 14, lines 9-10), and removing gas phase solvent by vacuum force (See column 13, lines 60+).

Therefore, it would have been obvious to combine Greiner with Allen et al, i.e it would have been obvious to use ***spraying*** **from a pressurized chamber through a narrow** ***nozzle*** of Smith instead of **batch soaking in an enclosed chamber** in Greiner to with the expectation of providing the desired coated elongated medical device of Greiner since Allen et al teach that it is well known in the art to use either ***spraying*** **from a pressurized chamber through a narrow** ***nozzle*** or **batch soaking in an enclosed chamber** to coat elongated materials using a *mixture* of the chemical modifier and SCF, and the typical spray deposition of the prior art is shown at Fig. 4a of US 4,734,451 to Smith. Clearly, one of ordinary skill in the art at would have reasonable

expectation of success in using teaching of Allen et al to remedy Greiner because both processes deal with coating of elongated materials with a chemical modifier from a mixture of the chemical modifier and SCF.

(B) Applicants argue that as to claim 21, none of the cited references disclose or suggest, "applying a vacuum force to a chamber containing the medical device," as in the claim. The Office action cites to col. 13, lns. 60+ of Smith as disclosing this feature, however, the cited portion of text addresses increasing the pressure in chamber 2 18, not applying a vacuum as recited in the claim.

At col. 13, lns. 61-66, Smith shows how to make a solution of the coating material in the SCF at high pressure since at col. 6, lines 57-64, Smith shows that solubility of high molecular weight solute often increases as pressure increases. However, further at column 14, lines 36-39 (which is covered by col. 13, lns. 60+), Smith teaches that operation under the high **vacuum** conditions in space would allow desirable conditions for thin films processes since the gas phase solvent is rapidly removed (See also Table 2).

(C) Applicants argue that as to claim 22, none of the references suggest or disclose "removing residual therapeutic from the supercritical fluid after collecting the supercritical fluid". While Allen includes a process flowchart, the process described does not include the step of collecting a mixture of supercritical fluid and therapeutic and then removing the therapeutic from the supercritical fluid. Rather, the flowchart only shows reusing a mixture of solvent and treatment mixture.

The Examiner respectfully disagrees with this argument. Allen teaches that in the chemical treatment with mixture comprising a modifying composition in a carrier SCF medium, the modifying composition is **separated** from SCF medium upon a pressure drop and applied to

the substrate to produce a modified substrate, and the carrier medium and any unused (residual) modifying composition can be collected in a recycling area 34 (where they are separated because of pressure drop) and recycled for further use (i.e. the chemical modifier is again interfaced with SCF) (See column 5, lines 42-48; column 6, lines 49-62).

(D) Applicants request to cite references to support rejection of claims 29-31.

Claim 31 is supported by Smith for the same reasons as discussed above in (B).

As to claims 29-30, Allen et al teach that the injector 30 having spraying nozzle (See column 2, lines 5-12) can be configured to inject the process fluids tangentially, perpendicularly, or at **any** other functional **angle** (claimed step of changing the location of an exit orifice or the direction in which SCF is directed towards the substrate) (See column 5, lines 49-53).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (571) 272-1429. The examiner can normally be reached on Mo-Thur. 9:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ELENA TSOY
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Primary Examiner
Art Unit 1762

March 8, 2005